HENRY FORD HOSPITAL

2799 West Grand Boulevard
Detroit, Michigan 48202

November 24, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 106 1
Rockville, MD 20852

RE: Docket No. 98N-0581

To Whom It May Concern:

I wish to provide comment on the proposed rule, "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents".

The proposed requirement for testing all autologous blood units collected for the listed infectious agents (610.40a), as well as the proposed requirement for supplemental testing on each donation found to be repeatedly reactive by a screening test (610.40c), will add millions of dollars of largely unrecoverable costs for hospitals and blood centers without appreciably affecting overall safety of components for patients, laboratory workers, or other hospital staff. Even if hospitals raise autologous blood charges, the chance of being fairly reimbursed for "duplicative" testing of multiple autologous donations is slim.

Most autologous units cannot be crossed over into the genera1 blood supply, secondary to low hemoglobin level or reactive infectious disease testing results on the first unit collected. American Association of Blood Banks Standard L1.120 (nineteenth edition, 1999) clearly requires segregation of autologous units and indicates these units are to be used only for autologous transfusion, except under well-documented, exceptional circumstances. Regulations already exist for the prominent labeling of autologous products found to be repeatedly reactive for infectious disease markers. Hospitals are committed to the principles of universal precautions, that is, treating **all** biologic materials as though they were infectious, whether or not such materials are so labeled.

At our facility, where autologous blood has been drawn and transfused for over 15 years, there has not been a single incident in which blood for an autologous donor was given to another patient. The first unit of autologous blood collected is tested for all infectious disease markers required for allogeneic donors, and the patient's physician and the patient are notified of any reactive results. The decision to perform supplemental testing is one made by the patient's physician, in consultation with the blood bank director.

The proposal to test all units of autologous blood for the listed infectious disease markers **may** help to further decrease a minuscule to theoretical risk, at the price of many millions of dollars that could be used to correct better documented threats to patient safety. However, the proposed requirement for supplemental testing of all succeeding donations which are repeatedly reactive for an infectious disease marker (if applicable to autologous donations), is clearly unneeded and should be eliminated.

At our institution, the additional cost of testing all autologous donations for the listed markers would be over $12,000 per year. While this amount may not seem significant in the eyes of your agency, it is an unnecessary and unneeded diversion of resources away from other, more well-documented initiatives, such as automated transfusion service technology, that would truly increase safety and accuracy of transfusions for patients.

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I would respectfully ask the agency to reconsider the above proposed changes. A requirement for testing of the first autologous blood donation collected within a 30 day period, with supplemental testing as medically indicated, as well as appropriate labeling of reactive units and segregation of autologous units, would serve to provide ample safety for patients and health care workers. I disagree that the magnitude of the safety gains to be made by adoption of the rule is large enough to justify the tremendous cost. Such a rule might paradoxically work against the best interests of patients, through the imposition of increased donation fees, which may not be covered by a patient's insurance policy, or would come from the patient's own pocket. Patients may thus be dissuaded from donating their own blood due to increased cost!

Sincerely,

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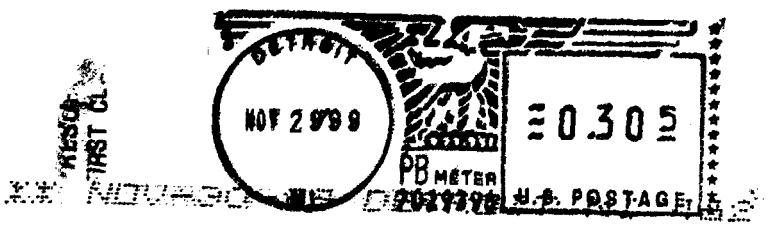

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